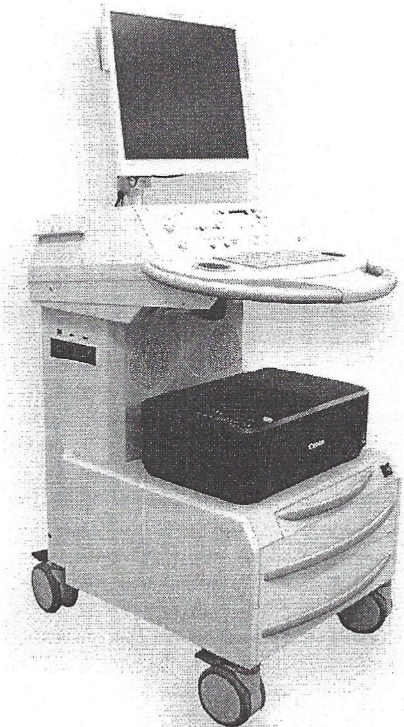
PARKS Medical Electronics, Inc.

Flo-Lab 2100-SX2 Bioengineering Manual



PARKS FLO-LAB, BIOENGINEERING MANUAL

TYPE B APPLIED PART
MEDICAL EQUIPMENT 🚶

Class II Non-Invasive Medical Device

THIS NON-INVASIVE SYSTEM MEETS THE SAFETY REQUIREMENTS SPECIFIED FOR A CLASS II ACTIVE MEDICAL DEVICE ACCORDING TO IEC 61140

This device meets these Standards:

ETL CLASSIFIED
Intertek

UL 60601-1 2003/04/25 ED: 1 Rev: 2006/04/26 Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety.

PMEI's Quality System is ISO 13485:2003 Certified

This device must be plugged into a **120 Vac, 60 Hz, 'HOSPITAL ONLY'** or **'HOSPITAL GRADE'** power outlet.

This device is manufactured by:

PARKS Medical Electronics, Inc.
19460 S.W. Shaw
Aloha, OR 97078 USA
Phone: 503-649-7007
Fax: 503-591-9753

Technical Support for the Parks Flo-Lab 1-888-356-9522

Monday - Friday 7:00 am to 3:30 pm Pacific Time

Mailing Address: P.O. Box 5669, Aloha, OR, 97006 USA
Shipping Address: 19460 SW Shaw, Aloha, OR 97078 USA
Fax: 503-591-9753 ~ e-mail: info@parksmed.com ~ Web Site: www.parksmed.com

INTRODUCTION

Thank you for choosing Parks Medical Electronics Computerized Flo-Lab. The Flo-Lab is a high performance, multi-function noninvasive vascular diagnostic system which utilizes today's most advanced technology to enable you to perform a variety of physiologic vascular examinations with greater accuracy and speed than ever before possible.

The Flo-Lab is the product of Parks Medical Electronics' over 30 years experience as a leader in production of vascular Doppler products, combined with feedback and input from users of our computerized vascular systems in hundreds of vascular laboratories worldwide since 1986. This system has a host of new features, many of which will be new to you, and we urge you to take the time to familiarize yourself with this manual to assure that you and your patients are getting the most out of your Flo-Lab.

OVERVIEW

The Parks Flo-Lab is a state-of-the-art instrument for the noninvasive physiologic assessment and diagnosis of peripheral vascular disease. This system combines all of the modalities needed to perform a broad range of vascular examinations, including:

Doppler Evaluation (Arterial, Venous & Periorbital)
Pulse Volume Recording (Arterial & Venous)
Segmental Pressures
Digital Pressures
Post Exercise / Reactive Hyperemia
Penile Pressures
Digital Waveforms
Venous Outflow (DVT)
Reflux (Chronic Venous Insufficiency)

MULTI-FUNCTION SYSTEM

The Flo-Lab combines Parks directional Dopplers, bilateral Pulse Volume Recording (PVR), and bilateral Photoplethysmography in a compact, ergonomic package. The Flo-Lab features a highly advanced, micro-processor controlled, cuff inflation system, which provides a new degree of smoothness, accuracy and precision to blood pressure measurements. Other new features offered on the Flo-Lab include: a new multi-sensor wireless remote control; an optional automatic cuff selector (controlled by the computer); and an integrated Multi-Mode display to simplify the selection of Flo-Lab user options.

The Flo-Lab has been designed with one goal in mind, to assist the user in producing vascular studies with a greater degree of accuracy, in less time, than was ever before possible.

WARRANTY

Parks Medical Electronics, Inc., warrants this Doppler Product against defects in materials and workmanship for a period of two years, one year for probes, 90 days for cuffs. Parks will, at its discretion, replace or repair free of charge, including labor and shipping, all parts to be defective and subject to such warranty.

This warranty does not apply to any instrument or probe not used according to instructions or damaged by abuse, accident, alteration, misuse, and/or tampering.

WARNINGS / HAZARDS

WARNING: MISUSE OF THIS EQUIPMENT AND INAPPROPRIATE ELECTRICAL CONNECTIONS WILL CREATE A SHOCK HAZARD. What appears to be simple connections to other equipment can place the patient and/or the operator at risk of electrical shock. **DO NOT** connect to an amplifier or intercom system. **DO NOT** connect items which are not specified as part of the original system.

FOLLOW THE MANUAL INSTRUCTIONS ON THE USE OF THIS EQUIPMENT. Avoid use involving electrical contact with other equipment. We assume no responsibility for misuse of our equipment.

WARNING: THE DRAWERS OF THIS UNIT ARE NOT SUITABLE TO USE AS A STEP OR FOR STANDING. These actions may cause the unit to tip and could result in physical injury.

WARNING: The multiple socket outlets of the power supply shall only be used for supplying power to equipment which is intended to form part of the system. Additional portable multiple socket outlets or extension cords shall not be connected to the system.

Power for the non-medical equipment supplied with the system (computer, monitor & printer) is intended to be supplied via the multiple socket outlets of the medical grade transformer supplied with the system. Plugging the non-medical equipment directly to wall power will compromise electrical safety and place the patient and/or the operator at risk of electrical shock.

WARNING: THIS EQUIPMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANAESTHETIC MIXTURES WITH AIR, OXYGEN OR NITROUS OXIDE. The possibility of explosion or fire always exists when this equipment is used in such an environment.

THIS EQUIPMENT SHOULD NOT BE USED WITH A DEFIBRILLATOR.

POTENTIAL ELECTROMAGNETIC OR OTHER INTERFERENCE: This Doppler may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Doppler, or shielding the location.

The Flo-Lab's IR remote receiver may respond to other IR equipment in the user's facility, which can interfere with the function of the Flo-Lab. If you suspect this is occurring, please contact Parks Technical Support at 1-888-356-9522. You may be provided with a corded remote to prevent further occurrences.

SUSCEPTIBILITY: This Doppler may experience a high pitched tone or buzzing noise from radio interference caused by a cell phone, mobile service or police station nearby. Interference may also be experienced from another Doppler, electrocautery or other sparking device, as well as defective fluorescent light fixtures or neon signs, if located in the close proximity.

INSPECT THE PROBE: Before using the probe, inspect for any cracks or breaks in the protective material covering the probe that could allow for ingress of conductive fluids such as acoustical coupling gel. Damage to the protective covering could create a shock or burn hazard if an uninsulated instrument is grounded and used with or touches other electronic equipment.

PHYSIOLOGICAL EFFECTS OF ULTRASOUND

IMPLANTED DEVICES

Implanted devices such as cardiac pacemakers should be avoided due to the possibility of affecting their operation. Some plastics used in replacement surgery may be affected by absorption of ultrasound energy. Metal implants may lead to reflections and as a precaution, avoid using ultrasound close to these.

STUDIES NEAR SENSITIVE TISSUES

Extreme care should be taken when treating areas near the eye because of the danger of damage to the retina. Similarly, extreme care should be taken near other sensitive nervous tissue. Based on experimental and epidemiological data, there is presently no identified risk associated with diagnostic ultrasound. However, a prudent and conservative approach is recommended in which diagnostic ultrasound should be used only for medical benefit and with minimal exposure.

THIS DOPPLER IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS ONLY.

ENVIRONMENTAL HAZARDS

There are no potential environmental hazards from the gels used with the probes.

CAUTION Dangerous Voltage Present:

With the top cover of the instrument removed and the power cord connected to an electrical outlet, there is dangerous voltage present in the diagnostic module. Use an isolated AC power source to avoid shock hazard.

WARNING: To avoid a tripping hazard and unnecessary damage, cables and hoses should be stored in the appropriate holders or cord wraps when not in use.

WARNING: Do not pull on cables and hoses to avoid unnecessary damage.

WARNING: PVR wave forms are subject to artifact due to room vibrations caused by air conditioning units, electric beds, treadmills and other electronic devices

WARNING: Front wheel brakes should be applied when the device is on an uneven surface.

WARNING: Use care with liquids in the vicinity of this device.

WARNING: This is a non-invasive vascular unit. Probes are only intended for surface level diagnostics, not subcutaneous use.

WARNING: The use of a non-shielded network cable may cause audible interference and artifact of Doppler wave form.

WARNING: To prevent hearing damage, make sure the Doppler volume is at a comfortable level when using headphones.

WARNING: Contraindication suggests that instrument not to be used for patients with blood clots or DVT if this is a known condition.

WARNING: Contraindication suggests that instrument not to be used for patients with recent surgery, ulcers, casts, or bandages that cannot or should not be compressed by pressure cuffs.

WARNING: Contraindication suggests that instrument not be used for patients who are post interventional procedure, IE, stent placement, arterial bypass graph.

WARNING: Contraindication suggests that instrument not to be used for patients with functioning dialysis access graph.

SPECIFICATIONS

DOPPLER

Pencil Probes:	High frequency (nominal 8 MHz). Low frequency (nominal 4 MHz). Optional skinny pencil probe (nominal 8 MHz).

The exact frequencies of the instrument are indicated by a label attached to the probe cable. Be sure to reorder replacement probes by these frequencies. DO NOT remove the label attached to the probe cable.

Output Filter:	User selectable for 28, 14, 7, 3.5 (Hz).
Output Select:	User selectable for normal or inverted recording.
Headphones:	Standard low-impedance stereo headphones.

PLETHYSMOGRAPH

PVR:	Pneumoplethysmograph (pulse volume recording).
PPG:	Photoplethysmograph. Sensor, Parks part # 832-8002-00.
Modes:	AC coupled (arterial mode pulsations only). DC coupled (venous mode gross volume changes).
Calibration:	PPG - none. PVR - user selectable calibrated pulse volume measurement. Pressure ± 2 mm @ 100 mm Hg, ± 5 mm above 100 mm Hg.

CUFF INFLATOR

Inflate modes:	Momentary (BP mode) or fill to preset (PVR mode).
Inflator Preset:	User selectable.
Inflation Rate:	BP mode - Linear, variable speed, user selectable 5-30 mm Hg/sec. PVR mode - fixed 30 mm Hg/sec.
BP Bleed rate:	User selectable 1-10 mm Hg/sec.
Valve type:	Variable flow & solenoid activated.
Verification/Calibration:	Cuff volume verification/calibration every 1000 hours or once a year. Volume ± 2%.

REMOTE CONTROL

Functions:	19 button, infrared remote for volume, position, size, mute, trace auto scale, cuff inflator and deflator, freeze, save, escape, invert, enter and four direction cursor.

PHYSICAL

Height:	56 inches.	142 cm.
Width:	22 1/2 inches.	57 cm.
Depth:	31 inches.	78.7 cm.
Weight:	117 pounds.	60.66 kg.

SPECIFICATIONS

ELECTRICAL

2110 Isolation Power Supply:	**120 Vac, 60 Hz.** 3 amps. Typical, 5 amps. Peak @ 120 Vac. The POWER cord must be plugged into a '**HOSPITAL ONLY**' or '**HOSPITAL GRADE**' alternating current power outlet.
19-B IR Remote Batteries:	**3 AAA alkaline, Parks part # 854-0001-00.**
Multi Port Inflator Power Supply:	12 Volt, 3.4 amps. Max current draw 1.2 amp Receives power from 2110 Isolation Power supply.

ENVIRONMENTAL CONDITIONS FOR TRANSPORT AND STORAGE

Ambient temperature:	Range, -40° F to 158° F (-40° C to +70° C).
Relative humidity:	10% to 95%, non-condensing.
Atmospheric Pressure:	Range, 500 hPa to 1060 hPa.

OPERATING CONDITIONS

IPXO rating:	Degree of protection against ingress of water ..... none provided.
Temperature range:	50° F to 104° F (10° C to 40° C).
Heat generated:	1706 BTU per hour.

MAINTENANCE & CLEANING

The Flo-Lab operator should see "MAINTENANCE" in the APPENDICES section of this manual.

Repair and Maintenance Literature is also located in PARKS **'Bioengineering Manual'**. Circuit diagrams, component part lists, descriptions, calibration instructions, and other information are supplied to assist qualified technical personnel to repair parts of equipment which are designated by the manufacturer as repairable.

Calibrate every 1000 hours or once a year.
See PARKS **'Bioengineering Manual'** for Cuff Volume Verification/Calibration.

For information on setting up, operating and servicing the computer and printer supplied with the Flo-Lab, see the **'Owners Manual'** or **'Users Guide'** supplied by the manufacturer of that equipment. These manuals or guides were included with the Flo-Lab when it was purchased.

Turn off power and unplug instrument from wall outlet before cleaning. Loose dust accumulated on the outside of the instrument can be removed with a soft cloth or small paint brush. Dirt which remains can be removed with a soft cloth dampened in a mild solution of detergent and water. Abrasive cleaners should not be used.

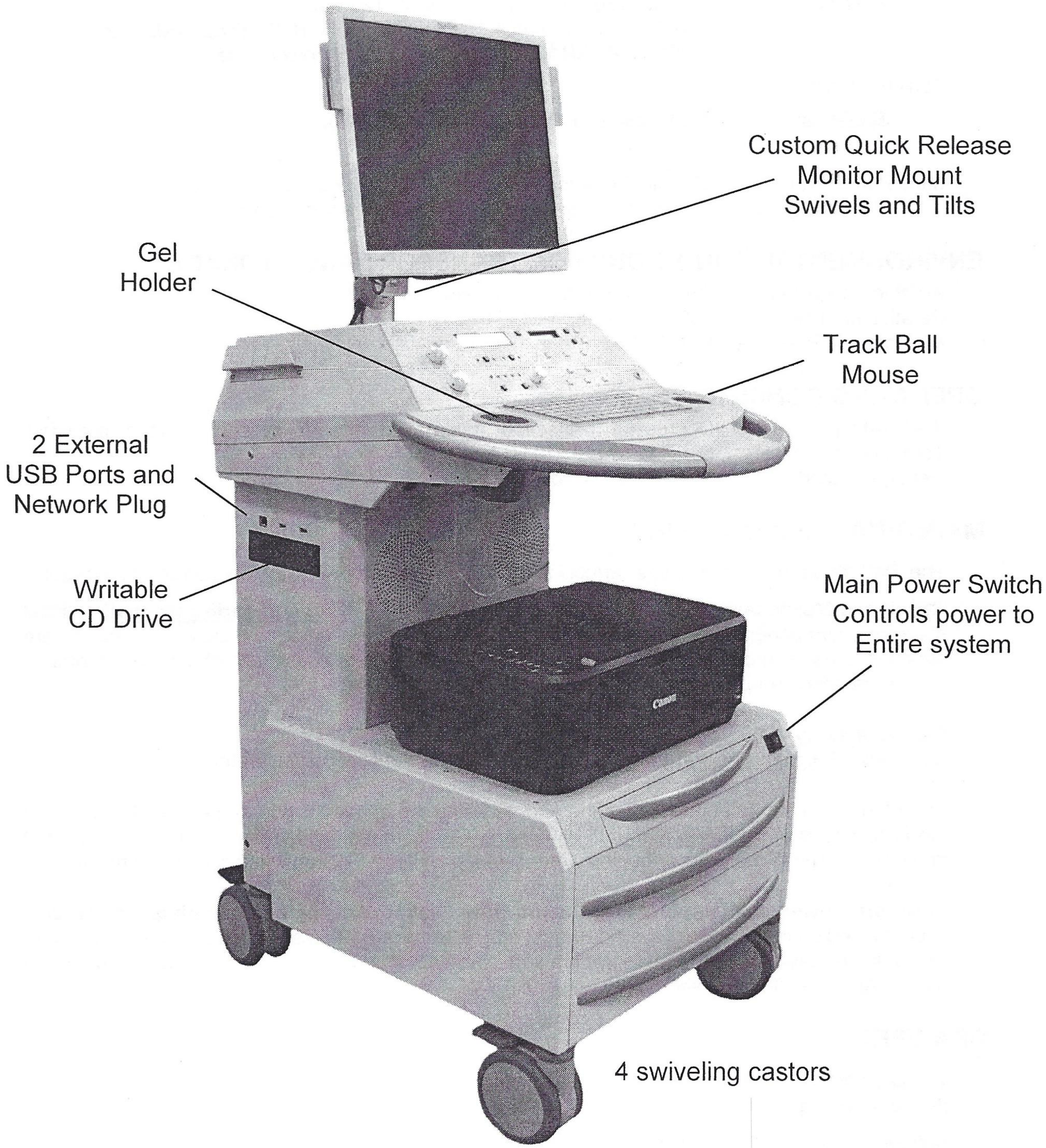
DRAWERS

Top Drawer: 14.75" x 12.75" x 1.5"
(Maximum weight limit 4lbs)

Bottom Drawers (x2): 15.5" x 17.5" x 3.75"
(Maximum weight limit 12lbs)

INSTRUMENT VIEWS

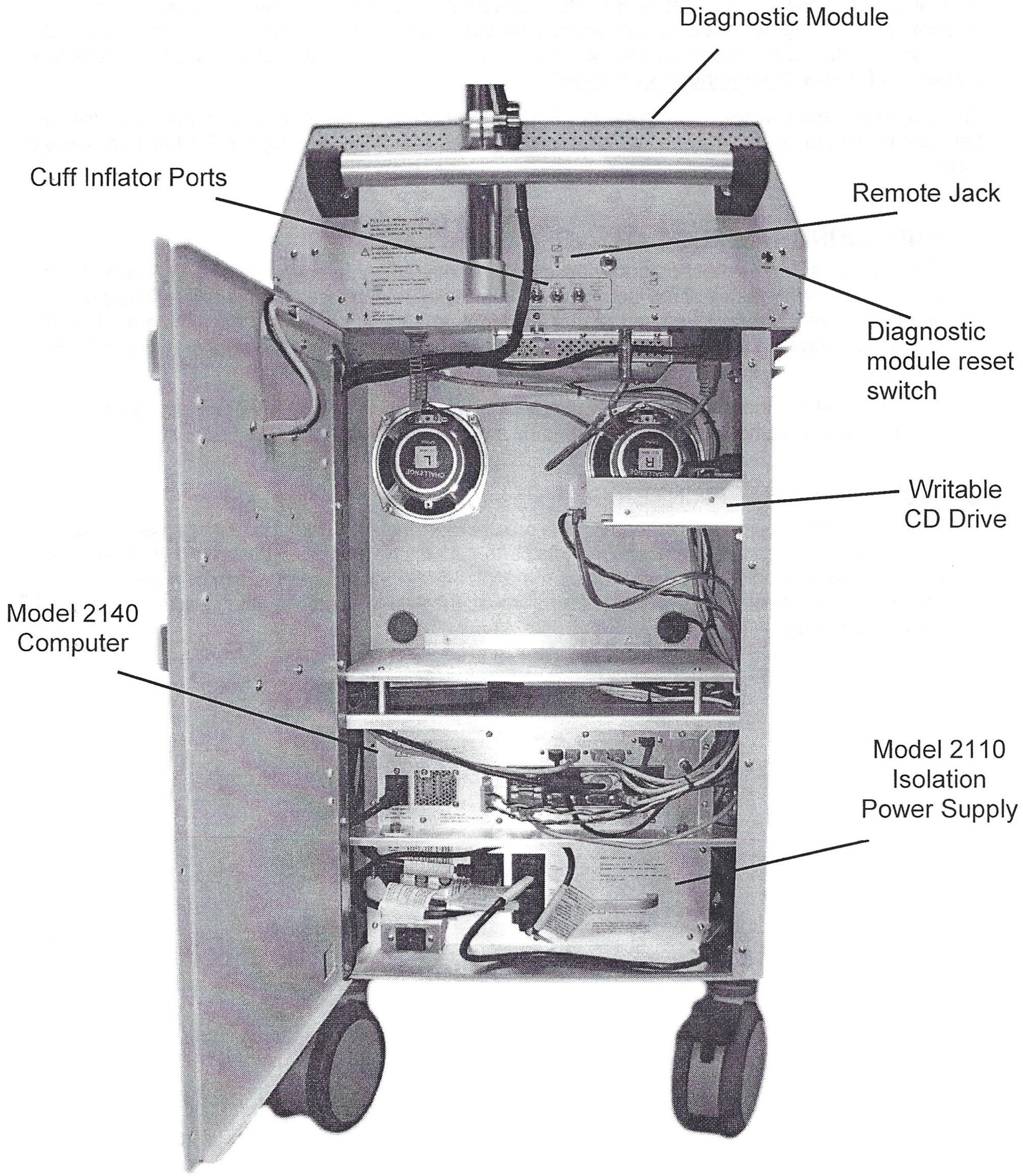
FRONT


Custom Quick Release
Monitor Mount
Swivels and Tilts
Gel
Holder
Track Ball
Mouse
2 External
USB Ports and
Network Plug
Writable
CD Drive
Main Power Switch
Controls power to
Entire system
4 swiveling castors

The Flo-Lab is furnished with a built-in isolated medical grade power supply. It must be plugged into a **120 V ac ~ 60 Hz** 'HOSPITAL ONLY' or 'HOSPITAL GRADE' power outlet via the external power cord. All power for the equipment furnished with the system must be supplied via the medical grade power supply. Plugging any equipment furnished with the system directly to wall power will compromise electrical safety.

INSTRUMENT VIEWS

BACK


Diagnostic Module
Cuff Inflator Ports
Remote Jack
Diagnostic module reset switch
Writable CD Drive
Model 2140 Computer
Model 2110 Isolation Power Supply

COMPONENT BACK PANEL ACCESS

Back door secured with five screws

"Class II Non-Invasive Device. Not for Subcutaneous use"

SETUP

With the system purchase, a representative of Parks Medical Electronics will visit your facility to assist in setting up the new Flo-Lab vascular system. Generally, it is preferred that the customer leave the instrument in its original shipping containers until the representative arrives on-site to perform the installation. With facility space limitations, this is not always practical. Setup instructions are also included in PARKS **'Bioengineering Manual'**.

The following steps outline the process your Parks representative will go through in preparing the Flo-Lab for patient studies, and may be helpful should the need ever arise to reship the Flo-Lab to a different facility.

A. UNPACKING THE FLO-LAB

The Flo-Lab is, for the most part, fully assembled at the factory and delivered nearly "ready to go". Though thoroughly tested at the factory as a complete system, prior to shipment the display monitor and color printer are removed and repackaged in their original containers for shipment. The Flo-Lab is then crated in its custom container, with all accessories stored within the drawers of the Flo-Lab cart.

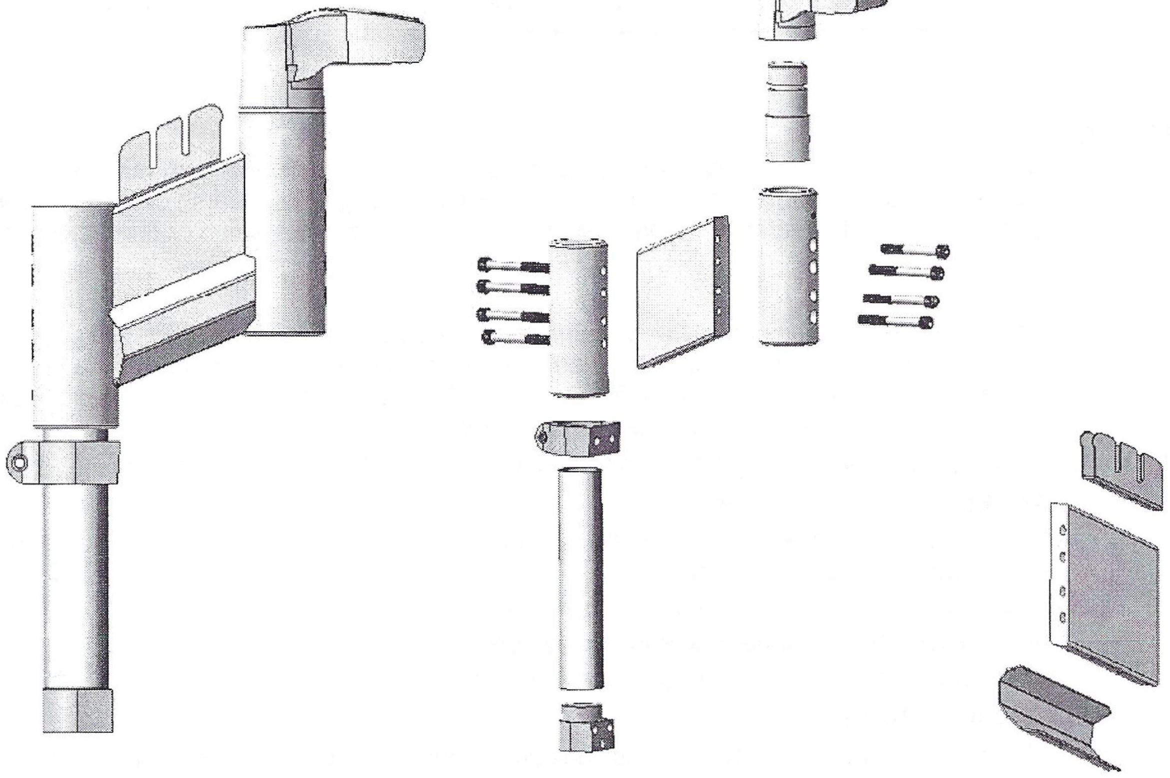
After the Flo-Lab, the display monitor, and printer are removed from their shipping cartons at the customer's facility, these containers should be stored, if possible, for future use.

B. INSTALLING THE PRINTER

The printer power cord and the printer cable are pre-installed in the Flo-Lab cart to ease installation. Once the printer has been removed from its carton, it may be placed on the printer shelf below the Flo-Lab, and the cables attached. Locate the printer information packet (shipped in one of the cart drawers) if you would like detailed information about setting up the printer, paper loading, and loading/replacing ink cartridges.

C. MONITOR MOUNTING BRACKET/CONNECTING THE MONITOR

The custom monitor mounting bracket tilts swivels and rotates for comfortable, ergonomic use. Upon arrival, the base of the bracket will be mounted to the back of the Flo-Lab.

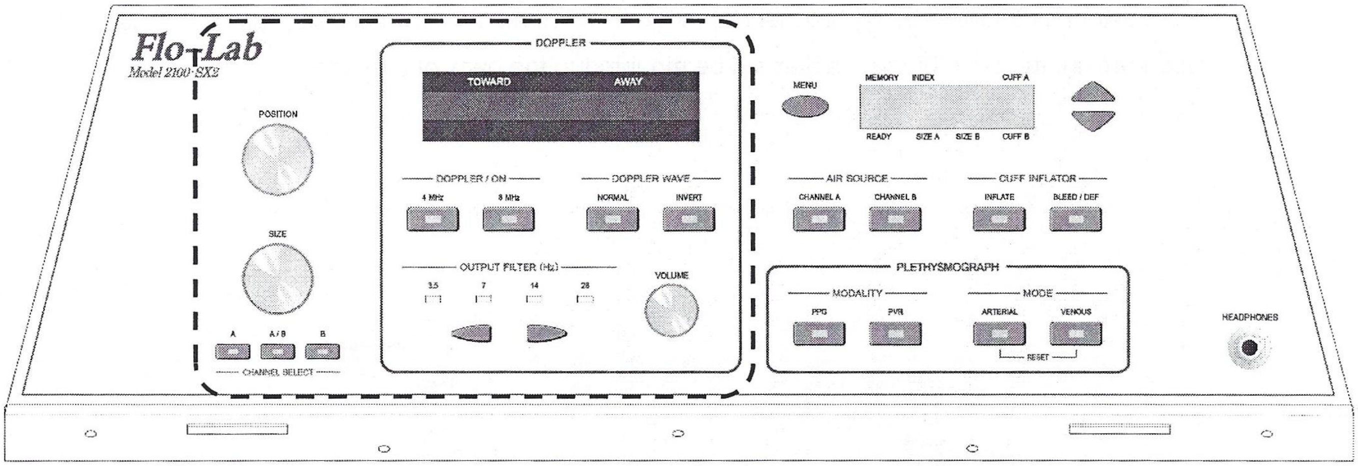


"Class II Non-Invasive Device. Not for Subcutaneous use"

DESCRIPTION OF CONTROLS

FRONT PANEL

A. DOPPLER SECTION


Flo-Lab
Model 2100-SX2
POSITION
SIZE
A
A / B
B
CHANNEL SELECT
DOPPLER
TOWARD
AWAY
DOPPLER / ON
4 MHz
8 MHz
DOPPLER WAVE
NORMAL
INVERT
OUTPUT FILTER (Hz)
3.5
7
14
28
VOLUME
MENU
MEMORY
INDEX
CUFF A
READY
SIZE A
SIZE B
CUFF B
AIR SOURCE
CHANNEL A
CHANNEL B
CUFF INFLATOR
INFLATE
BLEED / DEF
PLETHYSMOGRAPH
MODALITY
PPG
PVR
MODE
ARTERIAL
VENOUS
RESET
HEADPHONES

POSITION

This knob positions the waveform baseline up or down on the paper and monitor. This is a speed sensitive control, with a rapid turn of the knob making large, coarse changes in baseline position, while slow rotation of the position knob serves to make small or fine adjustments in baseline position.

SIZE

This knob changes the sensitivity, or gain of the instrument, allowing changes in waveform size (amplitude), or size, on the monitor. Size may be adjusted by the user at any time to increase or decrease the height of the waveforms, or may be adjusted to a "Preset" size factor prior to beginning testing (see Menu Display; Size Settings).

See page III . **30** in the appendices for techniques on better Doppler recordings.

CHANNEL SELECT (A, A/B, B)

When in bi-lateral mode (PVR or PPG), Channel Select allows the **SIZE** and **POSITION** to be set together or individually set.

A/B -- Adjusts the size or position for both A and B channels.

A – Adjusts the A channel size and position only.

B – Adjusts the B channel size and position only.

FLOW BAR GRAPH

Provides a display of Doppler signals, indicating both blood flow direction (relative to the probe) and relative blood flow velocities.

TOWARD

Display indicates flow Toward probe.

AWAY

Display indicates flow Away from probe.

DOPPLER / ON

If the Doppler is inactive, depressing either the 4MHz or 8MHz buttons activates the Doppler on the Flo-Lab with Doppler signal being displayed on monitor (if in a waveform screen) the active Doppler frequency (4 MHz or 8 MHz) will default to the last setting used. Plethysmographic modalities (PPG & PVR), if active, are automatically turned off.

4 MHZ

Light indicates nominal 4 MHz. The lower frequency is for deep vessels.

8 MHZ

Light indicates nominal 8 MHz. The higher frequency is for normal tests.

DESCRIPTION OF CONTROLS

FRONT PANEL

DOPPLER RECORDING

Pressing these buttons switch the recorder waveform to either normal or inverted orientation.

NORMAL

Flow toward the probe - Above

Flow away from probe - Below

INVERT

Flow toward the probe - Below

Flow away from probe - Above

OUTPUT FILTER - HZ

This control affects the smoothing of the recorded wave. It has no effect on what you hear. The numbers refer to the upper-frequency band pass of a 4-pole active filter. Higher numbers mean less smoothing but a more accurate reproduction of velocity changes. As you smooth the waveform by going to lower numbers, you are throwing away information. **Most recording is done using 3.5 Hz or 7 Hz.** This will reduce most unwanted noises and still render a good recordable signal.

3.5 Hz - Some detail and very smooth. **7 Hz** - Smoothed and detailed.
14 Hz - Some smoothing with more detail. **28 Hz** - Maximum detail.

◀ Left arrow (Decrease frequency button) steps to **more smoothing** and less detail.
▶ Right arrow (Increase frequency button) steps to **less smoothing** and more detail.

Refer to the “Basics” section in the Appendices (chapter V).

See page III . **25** in the Appendices for technical articles on “Using Probes”.

VOLUME

Knob adjusts loudness.

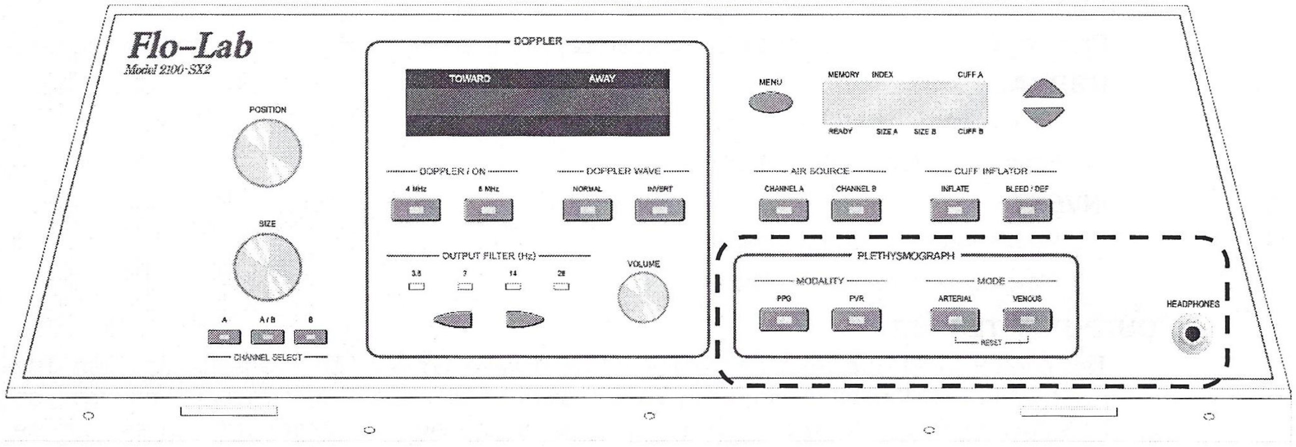
Refer to the “Basics” section in the Appendices (chapter V).

See page III . **25** in the Appendices for technical articles on “Using Probes”.

DESCRIPTION OF CONTROLS

FRONT PANEL

B. PLETHYSMOGRAPH SECTION


Flo-Lab
Model 2100-SX2
POSITION
SIZE
A
A/B
B
CHANNEL SELECT
DOPPLER
TOWARD
AWAY
DOPPLER / ON
4 MHz
8 MHz
DOPPLER WAVE
NORMAL
INVERT
OUTPUT FILTER (Hz)
3.5
7
14
28
VOLUME
MENU
MEMORY
INDEX
CUFF A
READY
SIZE A
SIZE B
CUFF B
AIR SOURCE
CHANNEL A
CHANNEL B
CUFF INFLATOR
INFLATE
BLEED / DEF
PLETHYSMOGRAPH
MODALITY
PPG
PVR
MODE
ARTERIAL
VENOUS
RESET
HEADPHONES

PPG

This button indicates, when illuminated, that the Photoplethysmograph is active, and that PPG signals will be displayed on the monitor. Pressing this button activates the PPG, and automatically deactivates the Doppler or PVR (if active).

PVR

Indicates, when illuminated, that the Pulse Volume Recorder is active, and that PVR signals will be displayed on the monitor. Pressing this button activates the PVR, and automatically deactivates Doppler or PPG (if active).

ARTERIAL

Indicates, when illuminated, that the instrument will display the plethysmographic (PPG or PVR) signals in Arterial, or “AC Coupled” mode. Pressing this button activates ARTERIAL mode and cancels VENOUS.

VENOUS

Indicates, when illuminated, that the instrument will display the plethysmographic (PPG or PVR) signals in Venous, or “DC Coupled” mode. Pressing this button activates VENOUS mode and cancels ARTERIAL.

RESET

In Arterial or Venous mode (active button light), pressing the button “zeros”, or “readies” PPG or PVR signal(s).

HEADPHONE JACK

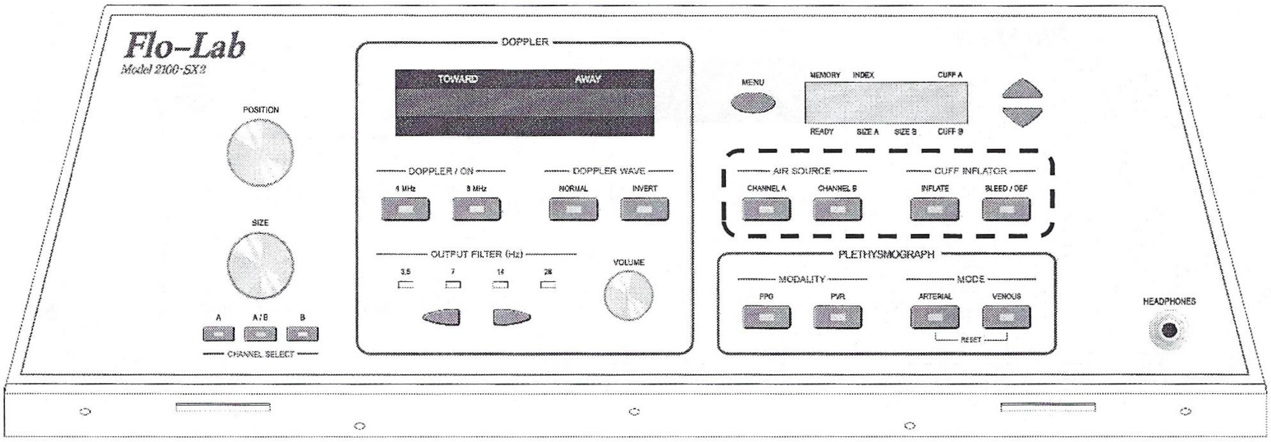
This jack provides an output for low-impedance stereo headphones. When they are plugged in, the speaker is disconnected. You always hear more using headphones, especially when checking weak flow or veins.

Note: In some cases an adapter is used to connect the headphones to the system. When they are not in use, the user must be careful to remove both the headphone jack and the adapter, to restore audible Doppler signals.

DESCRIPTION OF CONTROLS

FRONT PANEL

C. CUFF INFLATOR SECTION


Flo–Lab
Model 2100-SX2
DOPPLER
TOWARD
AWAY
POSITION
SIZE
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A/B
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CHANNEL SELECT
DOPPLER / ON
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14
28
VOLUME
MENU
MEMORY
INDEX
CUFF A
READY
SIZE A
SIZE B
CUFF B
AIR SOURCE
CHANNEL A
CHANNEL B
CUFF INFLATOR
INFLATE
BLEED / DEF
PLETHYSMOGRAPH
MODALITY
PPG
PVR
MODE
ARTERIAL
VENOUS
RESET
HEADPHONES

AIR SOURCE

CHANNEL A

This cuff inflator hose button selects the A channel air source. This is used for all blood pressure measurements, and for right limb PVR recordings. Pressing this button alternately activates/deactivates this channel.

CHANNEL B

This hose button selects the B channel air source. This is used for left limb PVR recordings only. Pressing this button alternately activates/deactivates this channel.

CUFF INFLATOR

INFLATE

The cuff inflator button is mode sensitive, with different operation depending upon the mode selected. If Doppler or PPG is active, the instrument defaults to “Blood Pressure” mode, with the cuff inflating (pumping) as long as the button is held depressed. In PVR mode, the function changes, with a single press of the button automatically filling the cuff(s) to the desired preset pressure (see, *‘Customizing your Flo-Lab; Multi-Mode Display; PVR Preset Pressures’*).

BLEED/DEF

This button is mode sensitive, with different operation depending upon the mode selected. In Doppler or PPG mode, with “Auto Bleed - OFF”, once the segmental or digit cuff is filled to the desired level, momentarily pressing the **BLEED/DEF** button activates a smooth, continuous bleed down of the pressure in the cuff at the selected bleed rate (see Customizing your Flo-Lab; Multi-Mode Display; Bleed Down Rate). While bleeding down, a second press of this button automatically rapidly deflates, or “dumps” the pressure in the cuff.

In “Auto Bleed - ON” mode (see, *‘Customizing your Flo-Lab; Multi-Mode Display; Auto Bleed’*), the cuff will automatically begin to bleed when the inflation is completed. There is no need to press bleed/deflate to begin the bleed down process. In this mode, pressing **BLEED/DEF** provides a rapid deflate, or “dump” of the cuff pressure.

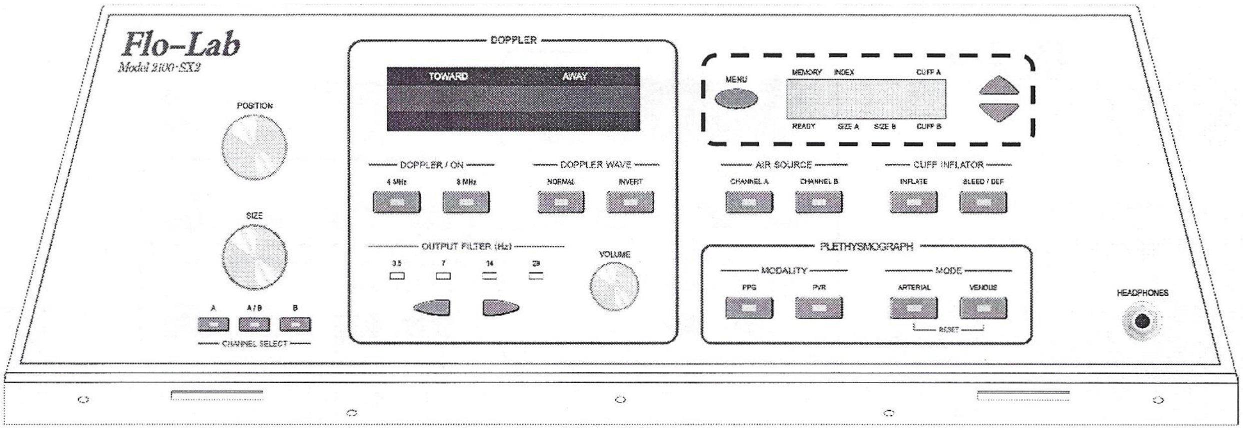
NOTE: For optimum performance of your Flo-Lab, use only the hoses furnished with the system. The calibration of cuff volume and volume change is based on using nine foot hoses and adapters as furnished. Any other length or size of tubing or addition of an in-line air chamber will cause the reported cuff volume to be increased or decreased by increase/decrease in volume.

“Class II Non-Invasive Device. Not for Subcutaneous use”

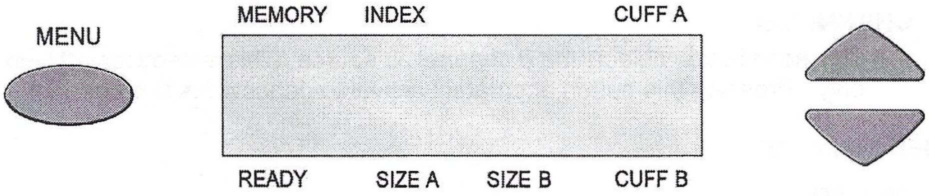
DESCRIPTION OF CONTROLS

FRONT PANEL

D. DISPLAY SECTION


Flo-Lab
Model 2100-SX2
POSITION
SIZE
A
A/B
B
CHANNEL SELECT
DOPPLER
TOWARD
AWAY
DOPPLER / ON
4 MHz
8 MHz
DOPPLER WAVE
NORMAL
INVERT
OUTPUT FILTER (Hz)
3.5
7
14
28
VOLUME
MENU
MEMORY
INDEX
CUFF A
READY
SIZE A
SIZE B
CUFF B
AIR SOURCE
CHANNEL A
CHANNEL B
CUFF INFLATOR
INFLATE
BLEED / DEF
PLETHYSMOGRAPH
MODALITY
PPG
PVR
MODE
ARTERIAL
VENOUS
RESET
HEADPHONES

The Multi-Mode display is a multiple menu screen, allowing the user to quickly change operational/functional settings on the Flo-Lab. Below is an explanation of the Multi-Mode display control buttons, followed by a description of what each menu screen does, and how displayed parameters/settings may be changed.


MENU
MEMORY
INDEX
CUFF A
READY
SIZE A
SIZE B
CUFF B

MENU

This button cycles, with each press, through each of different menu screens (14 screens).

UP ARROW BUTTON

This button increases the displayed setting/parameter, or "toggles" the selection if that selection is of a "YES/NO" or "ON/OFF" type.

DOWN ARROW BUTTON

This button decreases the displayed setting/parameter, or "toggles" the selection if that selection is of a "YES/NO" or "ON/OFF" type.

DESCRIPTION OF CONTROLS

FRONT PANEL

1. DEFAULT SCREEN

The Main Screen

The Main Screen is a Mode sensitive screen, with the top line differing slightly depending upon if the instrument is in PVR mode, or in DOPPLER or PPG mode (the top line is the same for DOPPLER and PPG modes).

2. MAIN SCREEN - PVR MODE

```
MEMORY   INDEX              CUFF A

60<PRESET                   0

RB         0        0       0

READY    SIZE A   SIZE B   CUFF B
```

When PVR is active, the top line displays the "Preset Pressure", which is the pressure the instrument will automatically fill PVR sensing cuff to. The Preset Pressure may be increased/decreased by pressing the UP/DOWN arrow buttons respectively, with the preset pressure changing in 5 mm Hg increments.

3. MAIN SCREEN - DOPPLER OR PPG MODE

```
MEMORY   INDEX              CUFF A

1:132-1.13                  0

RB        0         0       0

READY    SIZE A   SIZE B   CUFF B
```

When either **DOPPLER** or **PPG** are selected, the top line displays Memory & Index. *Should the Flo-Lab be operated without a computer hookup*, the Flo-Lab has internal memory allowing the capture and saving of segmental blood pressures for later, and automatically calculates the corresponding "indices", for manual transfer onto a form.

In this mode, the first position of the top line in the Multi-Mode Display is the Memory location label, with stored pressures and calculated indices appearing next to the location label. The first two memory locations are labeled RB and LB (for storing the Right and Left Brachial systolic blood pressures respectively), followed by labels of "1-18", for storage of up to 18 additional blood pressures. As blood pressures are saved in memory slots 1-18, the instrument calculates and displays the saved pressures "Index" (compared to the highest saved brachial pressure). The **UP** and **DOWN** arrow buttons are used to cycle up and down through each memory location for review and/or transfer of data.

"Class II Non-Invasive Device. Not for Subcutaneous use"

DESCRIPTION OF CONTROLS

FRONT PANEL

4. MAIN SCREEN - STANDARD FUNCTIONS

```
MEMORY   INDEX              CUFF A
60<PRESET                     0
AB        0         0         0
READY    SIZE A    SIZE B   CUFF B
```

SIZE Readout

SIZE A and **SIZE B** section of the Multi-Mode display Main Menu provide a digital readout of the size setting in use for any (PPG, PVR or DOPPLER) recording. The Size scale in use is 0 - 100 (%). A setting of 40, for example, means the Flo-Lab is recording at 40% of maximum gain instrument gain. **SIZE A** is for the A channel (normally the Right channel), **SIZE B** is for the B channel (normally the left channel). **SIZE A** is normally used for all Doppler recordings, as well as Right Channel PVR and PPG recordings. **SIZE B** indicates the size setting for Left Channel PVR and PPG recordings.

SIZE A and **SIZE B** are typically adjusted together (set to equal values) when performing bilateral recording, but may be separately set. To set Size A & B individually:

> Deactivate the channel you do *not* want to change by pressing the corresponding button (**CHANNEL A** or **CHANNEL B**) so that its indicator light is off. Turning the size knob will now change only the active (lit) channel Size setting.

The second channel may be adjusted in the same way, by deactivating the channel already set, activating the channel to be adjusted, and turning the **SIZE** knob. When each channel has been set to the desired level, both may now be switched back to active, with the system maintaining each channels individual size setting.

NOTE: Once both channels are active, turning the size knob further will always switch the Size setting back to "equal" - the B channel matching / equalizing to the A channel.

READY indicators

Ready indicators (the letters A & B, for the Right and Left channels respectively) appear when a Plethysmographic signal has been "zeroed" for display on the Monitor or Strip Chart Recorder. In PPG, ARTERIAL mode, READY occurs automatically after the PPG sensor has been positioned on the patient. In PVR, Arterial mode, READY occurs automatically after the cuff pressure has stabilized/settled. When zero is achieved (usually within 5 seconds), the letters "A" and/or "B" will appear in the display window.

In "Venous Mode" the zeroing of the waveform is not automatic, and requires pressing the **VENOUS** button. This is normally pressed after the PPG sensor has been positioned, or the PVR cuff has been filled to a stable level. When the zeroing sequence is complete, the "A" and/or "B" READY Indicators will appear in the display window.

Cuff A & Cuff B Pressure

Cuff A and Cuff B displays the air pressure currently in each/either cuff channel. Blood pressure is always measured using channel A (either DOPPLER or PPG mode). Bilateral PVR recordings fill both the Right and Left channel cuff simultaneously, displaying each cuff pressure as CUFF A & CUFF B respectively.

5. DESCRIPTION OF MENU SCREENS

SCREEN #1: PLETHYSMOGRAPH SETTLE TIME

Plethysmograph settle time allows the user to select the AC Mode "Auto-Zero Rate" applied to the displayed PVR & PPG waveforms - labeled as FAST, MEDIUM & SLOW (corresponding to how quickly the wave will re-stabilize itself). FAST provides the most stable waveform, but can alter some slower changing elements of the wave, resulting in wave distortion. Slow provides the most UN-affected (distortion free) waveform, but also shows a great deal of unwanted waveform "drift", such as respiratory artifact. In general, where waveforms are being viewed but not recorded/analyzed (such as when viewing a PPG signal to determine a Digit blood pressure), the FAST works best. When recording PVR and PPG waveforms for analysis, SLOW or MEDIUM should be used to minimize the filtering effect on important waveform elements.

SCREEN #2: SIGNALS A & B ARE SWAPPED/NOT SWAPPED

There may be circumstances where it is desirable to display signals "swapped", with channel A displaying the Left side signal (PPG or PVR), and channel B displaying the Right. In those instances, from this menu screen, pressing the **UP** or **DOWN** arrow buttons will toggle the selection.

SCREEN #3: CLEAR ALL INDICES

If the Flo-Lab memory locations built into the Multi-Mode Display have been used, pressing the **UP** or **DOWN** arrow buttons from this screen will clear all stored pressures and indices.

SCREEN #4: DUAL WAVEFORMS/SINGLE WAVEFORM

This controls how the strip chart recorder displays information **(If So Equipped)**. When Single Waveform is selected, the strip chart recorder operates as a single, 40 mm wide strip chart. When Dual Waveform is selected, the recorder operates as a two-channel strip chart, with 20 mm wide charts.

SCREEN #5: EXTERNAL SIGNAL ON/OFF

The Flo-Lab provides an external input on the back panel to allow other compatible devices (such as Parks Penile PVR module) to be connected and displays its output information on the computer monitor. Pressing the **UP** or **DOWN** arrow buttons toggles between the selected active Flo-Lab signal (DOPPLER / PVR / PPG) and the external device signal.

SCREEN #6: BP SLOW FILL RATE

When taking blood pressure measurements, the Flo-Lab cuff inflator starts off at a preset inflation rate of 30 mm Hg/second. In an effort to minimize over-inflation (to reduce testing time and patient discomfort), the Flo-Lab may be set up to slow the cuff filling rate. This screen gives the user the option of having cuff filling slow down to any fill rate they desire. From this screen the **UP** and **DOWN** arrow buttons may be used to select any Slow Fill Rate between 1 & 30 mm Hg/second. For most users, setting this rate between 12 - 15 mm Hg per second appears to be optimum.

SCREEN #7: BP SLOW FILL START

Though it's possible to have the Slow Fill Rate setting affect the entire inflation range, it is far more efficient (time wise) to all let the inflator fill at the standard fast rate up to a certain point, and *then* slow down to the Slow Fill Rate. This screen allows the user to select the level at which the Slow Fill Rate will begin. From this screen, pressing the **UP** and **DOWN** arrow buttons increases/decreases the slow fill Start Point, in 5 mm Hg increments. Best results seem to be with this point set between 90-100 mm Hg.

DESCRIPTION OF CONTROLS

FRONT PANEL

SCREEN #8: PVR CALIBRATION SEQUENCE ON/OFF

Users may elect to have the instrument calculate the pulse volume of PVR waveforms (in milliliters), or not. To choose to have the instrument make this calculation, turn PVR Calibration Sequence On, to not have the instrument calculate this information, choose PVR Calibration Sequence OFF. Pressing the **UP** and **DOWN** arrow buttons toggles between these two options.

SCREEN #9: PVR CAL A FACTOR

The instrument is provided with a Calibration Volume Chamber to verify the instrument is correctly measuring the cuff volume (a necessary component in the calculation of PVR waveform volume). This screen allows qualified personnel to adjust the displayed Channel A "calibration factor" until accurate volume measurement is achieved (Using the Calibration Volume Chamber). Refer to Bioengineering Manual.

SCREEN #10: PVR CAL B FACTOR

See Screen #9 above. This screen is used to adjust the Channel B calibration factor.

SCREEN #11: BLEED RATE

The user may select a bleed down rate that provides the best trade-off between measurement accuracy, and measurement time. The slower the bleed down rate, the more accurate and repeatable the pressure measurement will be. Too slow, however, may prove unnecessarily uncomfortable for the patient. Pressing the **UP** and **DOWN** arrow buttons will increase/decrease the bleed rate setting.

NOTE: AS A GENERAL RULE, the user should expect that there may be a blood pressure measurement error equal to the bleed rate setting (with a bleed rate setting of 3 mm Hg/sec, for example, blood pressure measurements may be off as much as 3 mm Hg). This error will be slightly less on patients with heart rates faster than 60, slightly more on patients with heart rates lower than 60. A setting of 2 - 4 mm Hg/sec is typically selected by users.

SCREEN #12: FIRMWARE VERSION

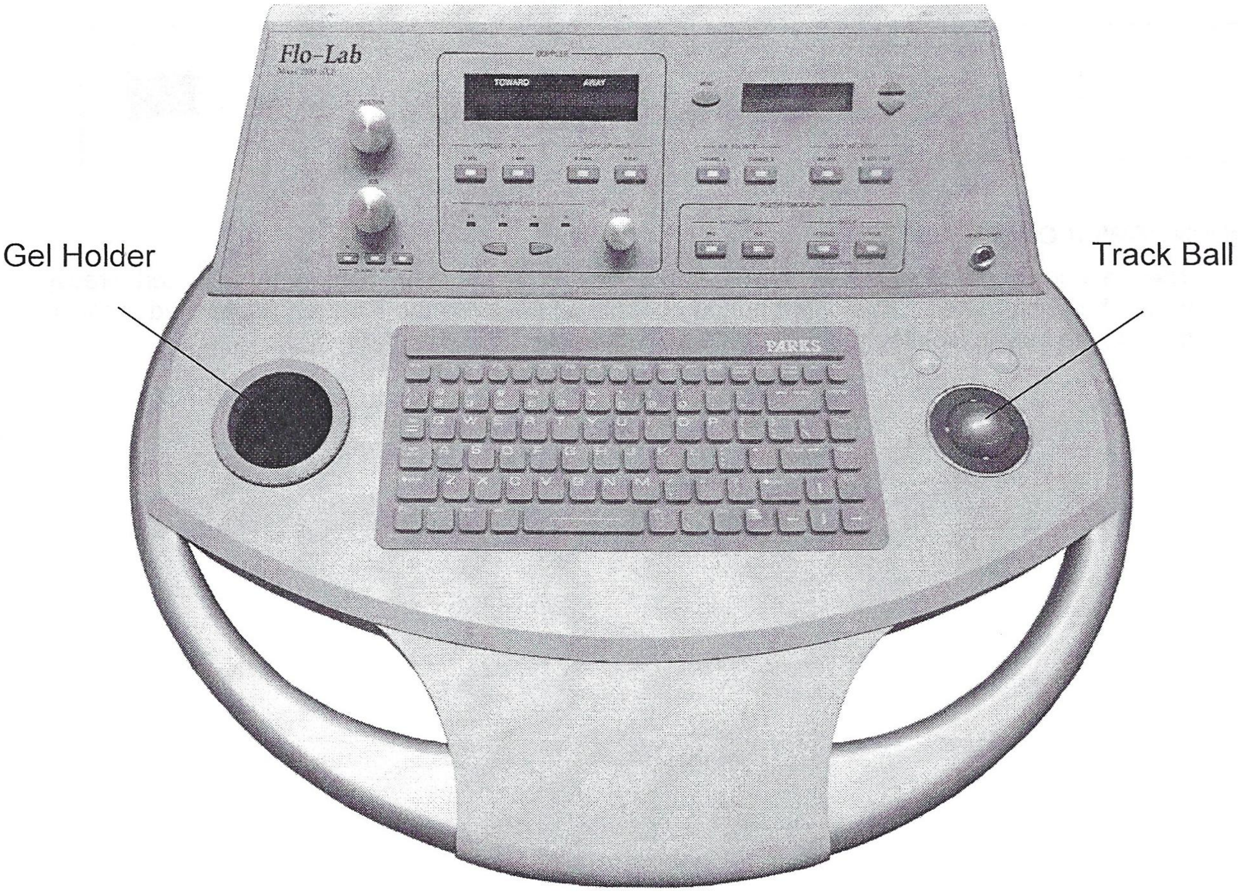
This screen displays the version of programming code used in the Multi-mode Display. It has no relation to the software version on the system main computer system.

SCREEN #13: AUTO BLEED ON/OFF

When taking blood pressure measurements, the user may choose to have the Flo-Lab begin cuff pressure bleed-down only *after* the **BLEED/DEF** button is pressed (Auto Bleed - Off), or to have the Flo-Lab begin bleed-down automatically after the **INFLATE** button is released (Auto Bleed - On). Pressing the **UP** and **DOWN** arrow buttons toggles between these options.

DESCRIPTION OF CONTROLS

LOWER FRONT PANEL



TRACKBALL

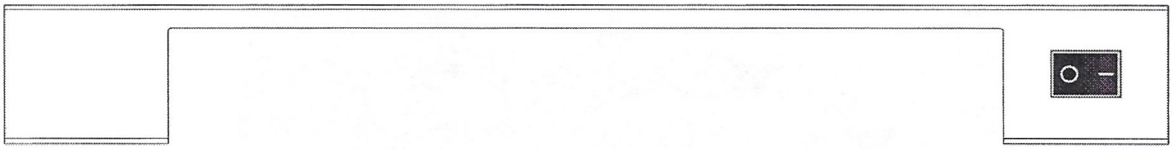
The trackball (mouse) manipulates your cursor when in Windows and the SonovaE software. Right Click button and left click button.

GEL HOLDER

Positioned to the left of the keyboard, the gel holder conveniently stores your gel bottles.

DESCRIPTION OF CONTROLS

LOWER FRONT PANEL UNDER THE PRINTER (FACING FLO-LAB)



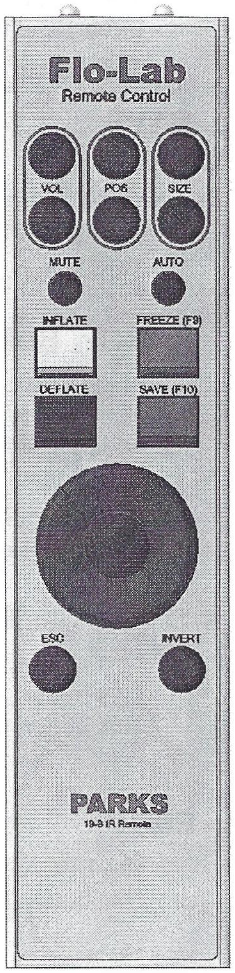
MAIN POWER ON/OFF SWITCH

The main power on/off switch for the Flo-Lab is located on the lower right front of the cart directly under the printer shelf. This on/off button controls all power to the Flo-Lab, printer and monitor, through the built-in isolated medical grade power supply.

DESCRIPTION OF CONTROLS

19-B IR REMOTE CONTROL

The Flo-Lab is equipped with a multi-function remote control, designed to enhance usability by placing the most frequently used controls conveniently in your hand.



VOL

Pressing the appropriate VOLUME button steps the audible Doppler sound higher or lower. Additionally, if the audible Doppler signal is "Muted", a press of **VOL** reactivates the Doppler audio (canceling MUTE).

POS

The POSITION buttons change the position of the wave on the screen. Up moves the wave towards the top of the screen. Down moves the wave towards the bottom.

This button works the same as the **POSITION** knob on the front panel.

SIZE

These buttons change the size of the wave form, either up or down, by increments of 10.

This button works the same as the **SIZE** knob on the front panel.

MUTE

Pressing this button turns off the Doppler audio until it is pressed a second time, or until the **VOL** button has been pressed. Pressing the **MUTE** button alternately turns the Doppler audio on and off without changing the Doppler volume setting.

AUTO

The AUTO SCALE button enables the user to change the waveform amplitude (DOPPLER, PPG, PVR). The **AUTO** button, when pressed, automatically adjusts the displayed waveform to fill 80% of the screen.

INFLATE

This button is mode sensitive, with different operation depending upon the mode selected. If Doppler or PPG is active, the instrument defaults to "Blood Pressure" mode, with the cuff inflating (pumping) as long as the button is held depressed. In PVR mode, the function changes, with a momentary press of the button automatically filling the cuff(s) to the desired preset pressure.

This is a duplicate of the **INFLATE** button on the Flo-Lab front panel.

DEFLATE

The BLEED/DEFLATE button is mode sensitive, with different operation depending upon the mode selected. In Doppler or PPG mode, with "Auto Bleed - OFF", once the segmental or digit cuff is filled to the desired level, momentarily pressing the **DEFLATE** button activates a smooth, continuous bleed down of the pressure in the cuff at the selected bleed rate (see Customizing your Flo-Lab; Multi-Mode Display; Bleed Down Rate). While bleeding down, a second press of this button automatically rapidly deflates, or "dumps" the pressure in the cuff.

In "Auto Bleed - ON" mode, the cuff will automatically begin to bleed when the inflation is completed. There is no need to press **DEFLATE** to begin the bleed down process. In this mode, pressing this button provides a rapid deflate, or "dump" of the cuff pressure.

This button on the remote is a duplicate of the **BLEED/DEF** button on the Flo-Lab front panel.

19-B IR REMOTE CONTROL

FREEZE

The FREEZE/UNFREEZE button is used in acquiring waveform or blood pressure test data throughout the software.

This button on the remote is a duplicate of the F9 key on the keyboard.

SAVE

The SAVE WAVEFORM or SAVE PRESSURE DATA button works either in conjunction with waveform FREEZE/UNFREEZE, or by itself, to save waveform or blood pressure test data throughout the software.

This button on the remote is a duplicate of the F10 key on the keyboard.

ARROW BUTTONS

In data acquisition screens, the UP, DOWN, LEFT, and RIGHT arrow buttons allow you to navigate from site to site in any order, or may be used to step back to review waves already saved. In addition, the Left and Right arrow keys may be used to move the waveform or blood pressure cursor using the software scroll function.

In data acquisition screens, the ARROW buttons on the remote are duplicates of ↑, ↓, ← and → on the keyboard.

ENTER

This button allows you to advance through the software program.
This button on the remote is a duplicate of the Enter key on the keyboard.

ESC

The ESCAPE button allows you to exit out of the current menu screen.
This button on the remote is a duplicate of the Esc key on the keyboard.

INVERT

When in the Doppler screen, INVERT switches the waveform to an inverted orientation. The Doppler recording on the Flo-Lab front panel will change to invert. Pressing INVERT again changes the waveform back to normal Doppler recording.

PLEASE NOTE:

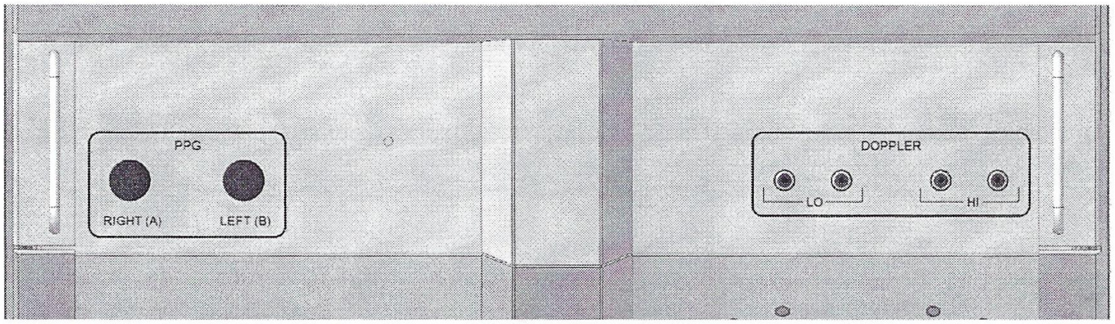
The Flo-Lab's IR remote receiver may respond to other IR equipment in the user's facility, which can interfere with the function of the Flo-Lab. If you suspect this is occurring, please contact Parks Technical Support at 1-888-356-9522.

THE BATTERIES IN THE 19-B IR REMOTE:

The cordless, 19-B IR remote uses 3 AAA alkaline batteries, Parks part # 854-0001-00 or acquire locally. They can be accessed by removing the two bottom screws on the side of the remote (one each side) and swiveling the small door open.

DESCRIPTION OF CONTROLS

CABLE CONNECTION PANEL (UNDER KEYBOARD)



⚠ PHOTOPLETHYSMOGRAPH JACKS

PPG A -- Photoplethysmograph probe jack (patient's right side).

PPG B -- Photoplethysmograph probe jack (patient's left side).

TYPE B APPLIED PART MEDICAL EQUIPMENT

Defined as having adequate protection against electric shock; meets current leakage requirements. Suitable for external use, NOT suitable for direct cardiac applications.

⚠ DOPPLER JACKS

HI -- Nominal 8 MHz DOPPLER probe jack.

LO -- Nominal 4 MHz DOPPLER probe jack.

Connection of Doppler probes

The exact frequencies of the probes are indicated by a label attached to the probe cable. When ordering new probes, be sure to order these frequencies. **DO NOT** remove the label attached to the probe cable

The Doppler can be used with PARKS:

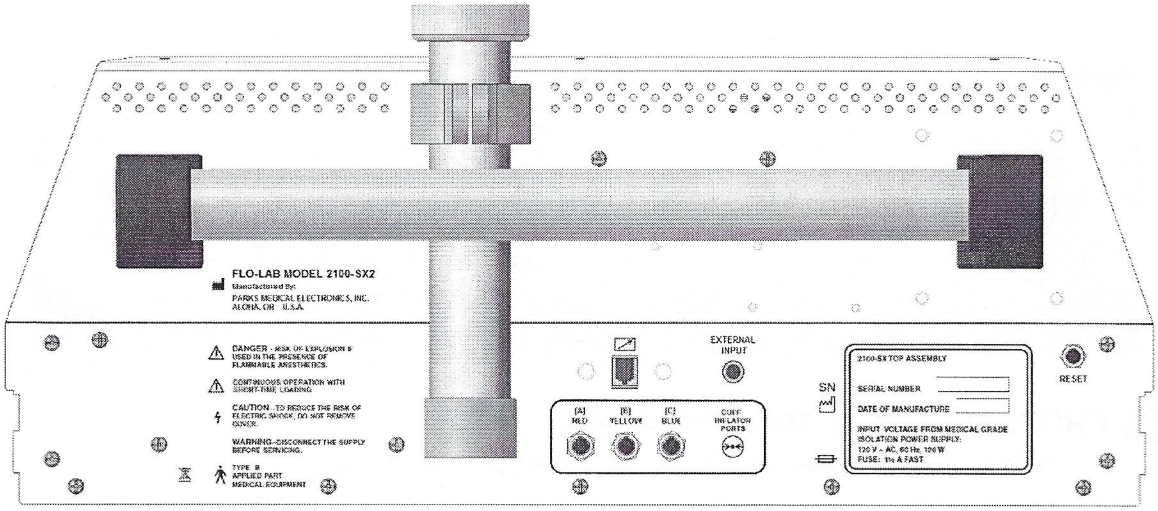
- **Standard high frequency** (nominal 8 MHz) 3/8" (10 mm) diameter pencil probe.
- **Skinny high frequency** (nominal 8 MHz) 1/4" (6.5 mm) diameter pencil probe.
- **Low frequency** (nominal 4 MHz) 1/2" (12 mm) diameter pencil probe.

DO NOT POINT THE ULTRASONIC BEAM INTO THE RETINA OF THE EYE.

THIS INSTRUMENT IS DESIGNED ONLY FOR VASCULAR WORK, NOT OBSTETRICAL SERVICE.

DESCRIPTION OF CONTROLS

DIAGNOSTIC MODULE


FLO-LAB MODEL 2100-SX2
Manufactured By:
PARKS MEDICAL ELECTRONICS, INC.
ALOHA, OR U.S.A.
DANGER - RISK OF EXPLOSION IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.
CONTINUOUS OPERATION WITH SHORT-TIME LOADING
CAUTION - TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE COVER.
WARNING - DISCONNECT THE SUPPLY BEFORE SERVICING.
TYPE B APPLIED PART MEDICAL EQUIPMENT
EXTERNAL INPUT
[A] RED
[B] YELLOW
[C] BLUE
CUFF INFLATOR PORTS
SN
2100-SX TOP ASSEMBLY
SERIAL NUMBER
DATE OF MANUFACTURE
INPUT VOLTAGE FROM MEDICAL GRADE ISOLATION POWER SUPPLY:
120 V ~ AC, 60 Hz, 120 W
FUSE: 1¼ A FAST
RESET

CAUTION Dangerous Voltage Present:

With the top cover of the instrument removed and the power cord connected to an electrical outlet, there is dangerous voltage present in the diagnostic module. Use an isolated AC power source to avoid shock hazard.

DANGER: RISK OF EXPLOSION IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

ϟ CAUTION DANGEROUS VOLTAGE

Warning, no user serviceable parts inside. Refer servicing to qualified service personnel.

TYPE B APPLIED PART MEDICAL EQUIPMENT

Defined as having adequate protection against electric shock; meets current leakage requirements. Suitable for external use, NOT suitable for direct cardiac applications.

MODE OF OPERATION: CONTINUOUS OPERATION WITH SHORT-TIME LOADING.

The Air Pumps for the Blood Pressure Cuffs shall be operated for a **maximum of four minutes continuously** and then allowed to cool to ambient temperature, which will take 1½ hours.

CUFF INFLATOR PORTS

RED / CUFF A

(RED) HOSE CONNECTION PORT

YELLOW / CUFF B

(YELLOW) HOSE CONNECTION PORT

BLUE / CUFF C

(BLUE) HOSE CONNECTION PORT

↗ REMOTE

Plug the infrared remote receiver (300-0277-00) into this jack.

FLO-LAB RESET

Very infrequently, the Flo-Lab may refuse to start. Use this RESET to clear the Flo-Lab without shutting down the entire system. However, **DO NOT** do so without first calling Technical Support toll free at 1-888-356-9522.

SEPARATE COLLECTION FOR ELECTRICAL AND ELECTRONIC EQUIPMENT.

Old instruments should not be disposed of in landfills.

⚠ “ATTENTION, CONSULT ACCOMPANYING DOCUMENTS”

These statements on the back panel apply to the connections directly under them on the Bottom Back Panel.

SAFETY ISOLATING TRANSFORMER (POWER SUPPLY)

Built-in isolated medical grade transformer supplies power to the Flo-Lab when plugged into an appropriate “HOSPITAL GRADE” alternating current outlet.

~ ALTERNATING CURRENT

POWER INPUT must match the ratings printed on the POWER SUPPLY PANEL and the MAIN POWER CORD PANEL.

120 V ac ~, 60 HZ, 120 VA.

ϟ CAUTION DANGEROUS VOLTAGE

Unplug the unit from the wall outlet before replacing the FUSE.

FUSE

Fuse, 1½ AMPERE, FAST.

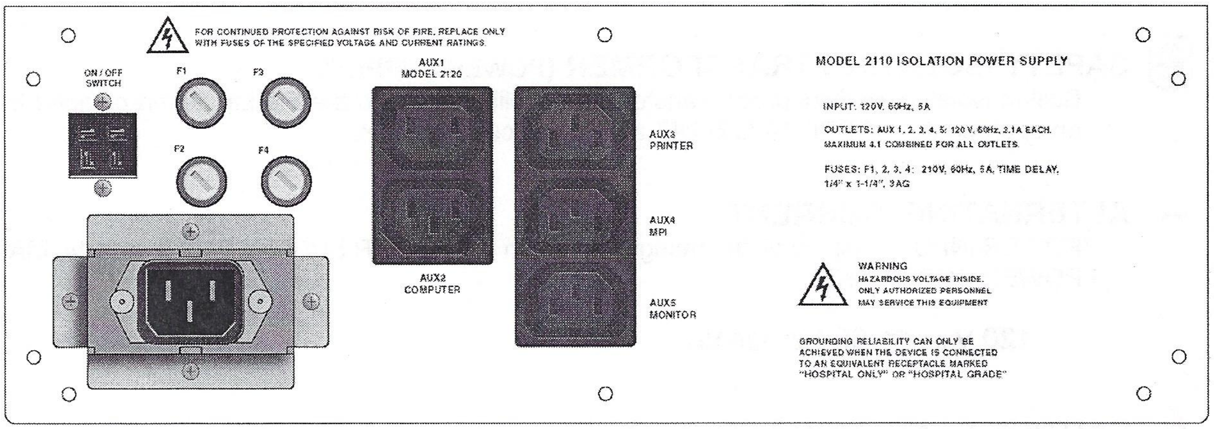
DESCRIPTION OF CONTROLS

2110 ISOLATION POWER SUPPLY

2110 Isolation E power supply is available for special power requirements of export units.

The Flo-Lab must be plugged into the outlet marked “Model 2120”. Usage for other outlets must not exceed what is specified on the panel.

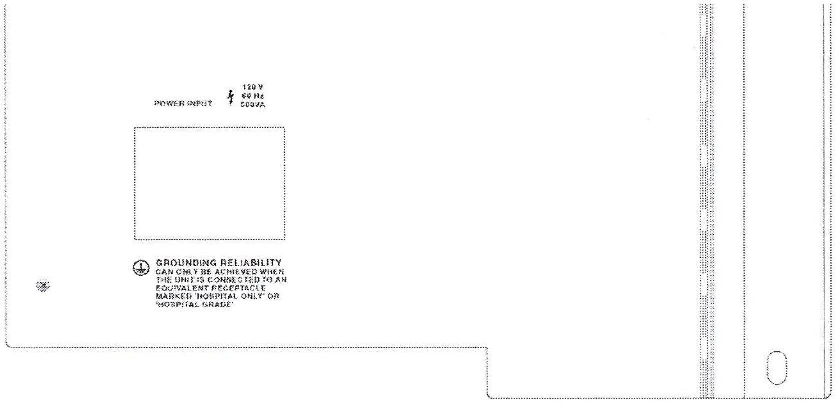
POWER INPUT must match the ratings printed on the POWER SUPPLY PANEL and MAIN POWER CORD PANEL.


FOR CONTINUED PROTECTION AGAINST RISK OF FIRE, REPLACE ONLY WITH FUSES OF THE SPECIFIED VOLTAGE AND CURRENT RATINGS.
ON / OFF SWITCH
F1
F3
F2
F4
AUX1 MODEL 2120
AUX2 COMPUTER
AUX3 PRINTER
AUX4 MPI
AUX5 MONITOR
MODEL 2110 ISOLATION POWER SUPPLY
INPUT: 120V, 60Hz, 5A
OUTLETS: AUX 1, 2, 3, 4, 5: 120 V, 60Hz, 2.1A EACH. MAXIMUM 4.1 COMBINED FOR ALL OUTLETS.
FUSES: F1, 2, 3, 4: 210V, 60Hz, 5A, TIME DELAY, 1/4" x 1-1/4", 3AG
WARNING
HAZARDOUS VOLTAGE INSIDE. ONLY AUTHORIZED PERSONNEL MAY SERVICE THIS EQUIPMENT
GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN THE DEVICE IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED "HOSPITAL ONLY" OR "HOSPITAL GRADE"

Safety isolating transformer

Four fuses, 5 ampere, TYPE 313 SLOW (internal)

BACK DOOR (LEFT SIDE)


POWER INPUT
120 V
60 Hz
500VA
GROUNDING RELIABILITY
CAN ONLY BE ACHIEVED WHEN THE UNIT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED 'HOSPITAL ONLY' OR 'HOSPITAL GRADE'

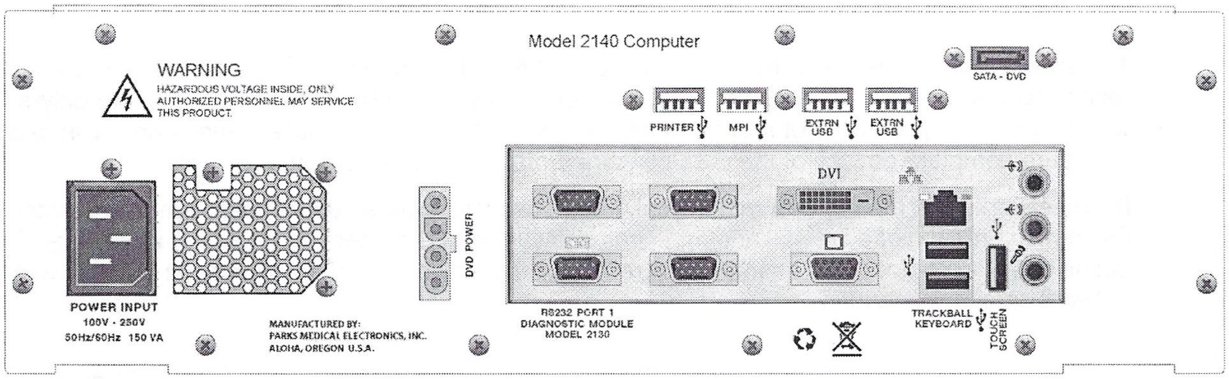
Protective earth (ground)

Dangerous voltage

“Class II Non-Invasive Device. Not for Subcutaneous use”

DESCRIPTION OF CONTROLS

2140 COMPUTER


Model 2140 Computer
WARNING
HAZARDOUS VOLTAGE INSIDE, ONLY AUTHORIZED PERSONNEL MAY SERVICE THIS PRODUCT.
SATA - DVD
PRINTER
MPI
EXTRN USB
EXTRN USB
DVI
DVD POWER
POWER INPUT
100V - 250V
50Hz/60Hz 150 VA
MANUFACTURED BY:
PARKS MEDICAL ELECTRONICS, INC.
ALOHA, OREGON U.S.A.
RS232 PORT 1
DIAGNOSTIC MODULE
MODEL 2130
TRACKBALL
KEYBOARD
TOUCH SCREEN

NOTE: This illustration is intended as guidance. The appearance of your particular unit's back panel may vary depending upon when your unit was purchased.

POWER INPUT

Power cord connects from the 2110 Isolation Power Supply to the input.

100-250V, 50-60 Hz, 150 VA

USB PORTS

Connects peripheral devices to the computer (Printer, MPI, Monitor, Keyboard, Trackball, Optional Temperature sensor and the diagnostic module). Each USB port is labeled for its intended use for optimal ESD shielding.

DVD POWER

Supplies power to the CD/DVD burner mounted on the left side of the cart.

eSATA - DVD

Connects to the CD/DVD burner; mounted on the left side of cart.

Connection for the monitor.

RJ-45 network connection.

DVI

DVI video input.

"Class II Non-Invasive Device. Not for Subcutaneous use"

FLO-LAB NETWORK RISK ADVISORY

THE SONOVAE SOFTWARE UTILIZES THE NETWORK FEATURE DICOM®.

To provide the safest and most secure operating environment for the Parks Flo-Lab it is recommended that the Flo-Lab not be connected to any computer network. This is the only sure way to avoid the possibility of malicious attacks, infections from computer viruses and worms and to ensure complete privacy of the data contained on the Flo-Lab computer system.

If the networking of the Flo-Lab with a local area network is required then Parks highly recommends the implementation of a firewall and anti-virus software with the latest updates and up-to-date virus definitions. Parks does not assume any responsibility for loss of data or system failures due to network security violations.

The Flo-Lab model 2100-SX2 runs on the Windows operating system. Parks encourages each facility to install and maintain the virus protection software used by your facility.

NOTE: To ensure that the SonovaE software runs optimally, do not run any virus scan or updates while in use on a patient.

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* DICOM ® is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

DOPPLER

In vascular testing the Doppler effect describes the change in frequency that occurs when a transmitted energy reflects from a moving object.

This formula describes the Doppler phenomenon:

$$\Delta F = \frac{2F_t V\ (\cos\theta)}{C}$$

Where:

Δ **F** = The difference between Doppler probe frequency transmitted and the frequency received.

$2F_t$ = Two times the transmitting frequency of the Doppler probe.

V = Velocity of insonated object (red blood cells).

θ (theta) = The angle of incidence between the ultrasound beam and the blood cells.

C = A constant which is equal to the velocity of ultrasound in tissue (1540 m/sec).

The formula appears intimidating but its principle is easy. It merely states that if you direct a sound beam at a moving object (here the Doppler ultrasound beam points at moving blood cells) that object's movement alters the frequency of the reflected sound beam. Blood cells moving toward the transmitter add their velocity to the signal causing the reflected signal to be a higher frequency than the transmitted frequency. Conversely, blood cells moving away from the transmitter subtract their velocity from the transmitted signal causing the reflected signal to be lower in frequency. The greater the velocity of the blood cells either toward or away from the transmitter the greater the frequency change that occurs. The signal that you listen to during Doppler testing is the difference between the transmitted and the received signal. The Doppler testing device compares the received signal's frequency to the transmission frequency and then outputs the difference between the two signals either to a recording device or to speakers or headphones.

Vascular testing uses two basic Doppler types: continuous wave (C.W.) and pulsed. Most C.W. Dopplers use two piezoelectric crystals (see note below), one continually transmitting and one continually receiving. Pulsed Dopplers use a single crystal which alternates between transmitting and receiving. Each type has unique advantages. C.W. Dopplers provide greater signal resolution and frequency response. Pulsed Dopplers (because of signal timing) allow more accurate determination of vessel depth. Because signal quality is usually more important than vessel depth information in noninvasive vascular testing, the Dopplers used on Parks equipment are continuous wave.

NOTE: Piezoelectric crystals change thickness rapidly when a high frequency electric current passes through them, resulting in the production of sound waves. When they are struck by sound waves reflected from the moving blood cells they convert the sound energy into electric current.

The Doppler unit transmits at a set frequency and "listens" for the returning echo. By comparing the frequency of the "echo" to the transmitted frequency, the Doppler determines forward or reverse flow, flow velocity (angle dependent) and the magnitude of the movement.

There are many elements that interplay to determine some of the values mentioned above but for everyday testing all you need to remember is that if the reflected signal is a higher frequency than the transmitted frequency it is usually associated with forward blood flow (flow towards the probe) and if it is a lower frequency it is reverse flow (flow away from the probe). On the strip chart recorder or on a scope forward flow usually appears as an upward deflection of the trace while reverse flow appears as a downward deflection.

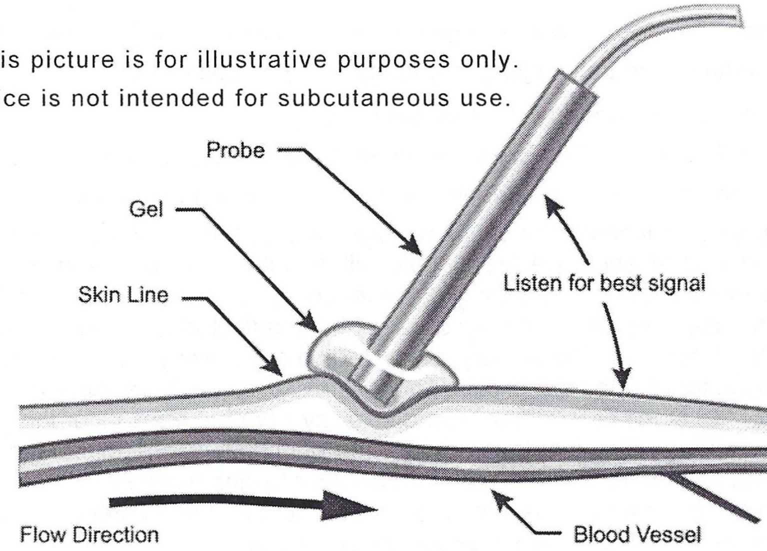
You can use Dopplers for both arterial and venous examinations. In arterial studies you compare the waveforms to known normals to establish a diagnosis. With venous studies, recording the Doppler signal yields little useful information. Venous Doppler studies rely heavily on the experience of the technologist to listen to and evaluate flow characteristics and they are the most subjective of the noninvasive examinations. In both arterial and venous tests the examination techniques are similar for the upper and lower extremities.

Normally you should use the high frequency Doppler probe for high flow, relatively shallow vessels. Use the low frequency probe for deeper vessels.

PROBE POSITIONING

PROPER PROBE PLACEMENT AND PROPER USE OF GEL ARE VERY IMPORTANT!

In vascular testing the ideal Doppler angle would be to have the probe pointing right down the vessel lumen. Since such a practice is impractical in normal testing a compromise exists. Hold the probe at a **45** to **60 degree** angle from the skin line with the probe tip pointing cephalad (toward the head). (see figure) As with all guidelines this is not a hard and fast rule. You must still search for the best quality signal.



Note: This picture is for illustrative purposes only. This device is not intended for subcutaneous use.

Figure B-1 *Proper Doppler Probe Angle*

Improper probe position alters waveform morphology. You cannot make an abnormal signal appear normal by repositioning the probe but you can make a normal signal appear abnormal by incorrect probe angle.

You must be very careful about probe pressure, because a slight amount of pressure against the skin can occlude the artery.

DO NOT point the ultrasonic beam into the retina of the eye.

THE RED PROTECTIVE COVER MUST BE REMOVED FROM THE PROBE BEFORE USE.

THE COUPLING GEL

You must use gel in front of the probe.

We recommend you use a coupling gel made especially for ultrasound. Don't use a gel that is too thin. You can use sterile jellies internally.

Ultrasound coupling gels are available from us, or will usually be available from one of your surgical supply dealers. These gels are available in bulk, sterile packets and bottles. Gel in a semi-rigid tube with a small extended tip is easier to use than that which is in collapsible tubes. Refilling from bulk is much less expensive than buying more bottles or packets. Some tubes can be autoclaved.

Please do not use ECG paste or cream. The probe crystals are covered by a material that is vulnerable to attack by excessive heat and ECG paste.

In an emergency use any sterile liquid or gel without excessive bubbles. Petroleum jelly or mineral oil can be used in emergencies, but they often do not transmit the sound well. Sensitivity may be reduced and bubbles in the gel can make a popping noise. Placing the pencil probe directly on wet tissue will also work.

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MAINTENANCE

REPAIR

Repair and Maintenance Literature is also located in the '**Bioengineering Manual**'. Circuit diagrams, component part lists, descriptions, calibration instructions, and other information are supplied to assist qualified technical personnel to repair parts of equipment which are designated by the manufacturer as repairable.

CLEANING THE INSTRUMENT

TURN OFF POWER AND UNPLUG INSTRUMENT FROM WALL OUTLET BEFORE CLEANING. Loose dust accumulated on the outside of the instrument can be removed with a clean, soft cloth. Dirt which remains can be removed with a soft cloth dampened in a mild solution of disinfectant and sterile water. Abrasive cleaners should not be used.

CLEANING THE PROBES

CLEANING THE PROBE

- Remove the gel with a soft tissue after each use.
- Wash any dried gel off the probe with warm running water.
- User may opt to wipe probe with alcohol, surface germicidal cloth, or liquid disinfectant (do not soak). Rinse probe with warm water to remove any residue after cleaning/germicidal agent dries. DO NOT USE BLEACH.

DO NOT AUTOCLAVE THE PROBE

Temperatures above **57.2** degrees Celsius (135 degrees Fahrenheit) destroy the crystal activity and cause the covering over the individual cables and the outer sheath to shrink and crack. With a raised temperature, a severe loss of sensitivity will occur. Autoclaving voids the probe warranty.

CLEANING CUFFS

If you need to wash the cuffs, remove the bladder first. The cuff covers are made of Nylon and Velcro, and may be washed by hand or washed in a washing machine using the gentle cycle. Hang the cuff on a line to dry.

CLEANING THE MANOMETER

Remove loose particles with a soft cloth or small brush. Wash with a soft cloth dampened in a mild solution of detergent and water. Never use abrasive cleaners. To disinfect surface, use a soft cloth dampened with liquid disinfectant or use a surface germicidal cloth. After cleaning/germicidal agent dries, remove any residue with a soft cloth dampened with water.

REPLACEMENT OF INTERCHANGEABLE AND / OR DETACHABLE PARTS

Nominal 8 MHz Doppler Probe

Nominal 4 MHz Doppler Probe

PROBES

The Doppler probes are easily ruined through misunderstanding and neglect. Over 90% of the failures of the Doppler are due to failure of the probe in some way.

THE PROBE FREQUENCY MUST MATCH THE TUNING OF THE DOPPLER.

The exact frequencies of the instrument are either engraved on the probe or are indicated by a label attached to the probe cable. Be sure to reorder replacement probes by these frequencies. A variation of .1 MHz is not significant at around 5 or 10 MHz. But it is around 2 MHz.

DO NOT remove the label attached to the cable. Probe warranty void if removed.

The active part of the probe consists of two crystals. One for transmitting ultrasound waves and the other for receiving reflected waves. The probe is connected to two jacks. It doesn't matter which side of the probe is connected to which jack.

DISCONNECTING THE PROBES from the instrument should be minimized.

Don't do it unless you need to, for two reasons. First the connectors wear and make erratic contact causing "static" after many disconnects. Second, people have a tendency to pull on the cable instead of the connectors themselves and they break the soldered connection inside the cable connector.

If the probe connectors or panel jacks are making poor contact and there is "static", the center pin wiping on the panel jack is usually at fault. A sharp tool can be used to bend the wiping sleeve inward and stop the noise.

THE DOPPLER CAN BE USED WITH:

Standard high frequency (nominal 8 MHz) 3/8" (10 mm) diameter pencil probe.
Skinny high frequency (nominal 8 MHz) 1/4" (6.5 mm) diameter pencil probe.
Low frequency (nominal 4 MHz) 1/2" (12 mm) diameter pencil probe.

The user should keep spare probes of the proper frequency on hand.

This instrument is designed only for vascular work, not obstetrical service.

STRANGE NOISES FROM THE DOPPLER

On occasion there are noises you might not expect from the Doppler when in fact the Doppler is working fine. The following are some common concerns and their causes.

CONCERN	CAUSE	REMEDY
Popping scratchy noises when the probe is first placed on the skin.	Air bubbles in the gel are moving and/or popping. Hair movement can also cause these noises.	Use a new dab of gel that looks clear, push the probe down enough so hair is immobilized, and wait a few seconds for everything to settle. If the noise is not there when the probe is clean (no gel) and suspended in the air, the Doppler and/or probe are probably working fine.
Static when the dry probe is moved through the air.	Loose connectors where the probe connects to the instrument, broken shield wire in the cable either at the connector or as it comes out of the probe.	There is normally some static generated when the cable is flexed, but it isn't severe. Replace probe or get connectors fixed. If the problem persists contact your sales representative.
High pitched tone and flow indicators go to the extreme.	Radio interference from a mobile service, police station nearby, even another Doppler working close by. Usually occurs near large open windows, rarely in the center of the building.	Move the Doppler to another location away from windows and toward the center of the building. If the problem persists contact your sales representative.
Buzzing noise that almost obliterates the Doppler signal.	Electrocautery or other sparking device, bad fluorescent light fixture or neon signs nearby.	Move the Doppler to another location away from the interference. If the problem persists contact your sales representative.
Howling noise when probe is held or laid on a table with gel on it.	Probe is acting as a microphone and you are getting acoustic feedback.	Wipe gel from probe, If the noise does not occur without gel on the probe, it is probably working fine.

ADDITIONAL TESTS:

1. Use the other frequency on your instrument to see if you have the same or similar problems.
2. Try using headphones if you have a howling noise. If there is no howl using headphones but there is with a speaker, it is acoustic feedback.
3. Try a different probe, even if it is the wrong frequency it will let you know if the problem is noisy connectors in the instrument or frayed shielding near the probe body.

SUMMARY

The problem may simply be a probe or it may be peculiar to the environment in which it is used. If you have tried the tests and remedies mentioned and you still suspect a problem contact technical support at 1-888-356-9522. Hours are Monday - Friday 7:00 am to 3:30 pm Pacific Time.